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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,536	12/12/2003	Donald J. White JR.	7858MD	9705

27752 7590 01/25/2006

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,536	WHITE ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 06 Feb 2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Requirement for Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to an oral composition, classified in class 424, subclass 57.

II. Claims 7-9, drawn to a method of providing surface conditioning effects to a subject's teeth and mucosal surfaces, classified in class 514, subclass 900 plus.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case invention I can be used to remove food causing an offensive odor, to freshen the breath or to remove scuffs on shoes.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Emelyn Hiland on January 11, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 2, 3, 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Glandorf (US 6,187,295).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this

application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Glandorf teaches composition for reducing the astringency of dentifrice compositions containing stannous. The dentifrice composition comprise of stannous ion preferably at levels ranging from 3,000 to 15,000 ppm (col. 30, lines 56), as recited in claim 6. Polyphosphates are incorporated into the dentifrice compositions to reduce the astringency as well as to reduce staining caused by the stannous compounds (col. 1, lines 1-18), as is recited in claim 5. The polyphosphates preferred for the disclosed composition are those having around four or more phosphate molecules, e.g., polyphosphates having 6, 13 and 21 repeating phosphate monomers (col. 4, lines 29-47). These polyphosphates are substantially the same as those described in the disclosure of the instant application (page 6). The compositions also included surfactants such as polyoxyethylene and polyethylene glycol (example VII), polymers included in claim 3, e.g., poly(ethylene glycol). The compositions disclosed by the reference comprise substantially the same compounds as the compositions disclosed and claimed by the Applicant. Accordingly, in regards to claims 1 and 2, one would have reasonably expected that the compositions of the reference have substantially the same properties, such as aesthetics, chemical properties and cleaning capabilities, as the applicant's compositions, since the compositions of the reference and the compositions of the instant claims are substantially the same. The reference anticipates the claims insofar as it discloses dentifrice compositions comprising polymeric surface-active agents and stannous ion sources.

2) Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Zerby et al. (US 5,451,401).

Zerby et al. teaches oral compositions including dentifrices, oral rinses and gels comprising polyphosphonic acid esters as tartar control agents, which encompasses the polyphosphonates recited in claim 4. The compositions may also comprise water-soluble fluoride ion sources such as stannous fluoride (SnF_2) in which the fluoride ions are at the level of 10 to 5000 ppm (about 30 to about 15630 ppm of Sn ions, the ppm of Sn values are calculated using the molecular formula of SnF_2 and the molecular weights of the individual atoms) (col. 8, lines 36-48), which encompasses what is recited in claim 6. Various anionic polymeric polycarboxylates and their complexes may also be used in the taught dental compositions (col. 8, lines 49-55), which is recited in claim 3 and encompasses the polymeric surface-active agent of claim 1. Pharmaceutical actives, such as pyrophosphate salts, may be added to the dental compositions. It is an inherent property of pyrophosphate salts to decrease staining due to stannous components (US 5,145,666)[1], as recited in claim 5. Anti-plaque and anti-gingivitis pharmaceutical actives that may be used in the compositions include stannous ions (col. 8, lines 36-68). The compositions disclosed by the reference comprise substantially the same compounds as the compositions claimed by the Applicant. Accordingly, in regards to claims 1 and 2, one would have reasonably expected that the compositions of the reference have substantially the same properties, such as aesthetics, chemical

[1] See, e.g. Lukacovic et al. col.1, lines 50-53.

properties and cleaning capabilities, as the applicant's compositions, since the compositions of the reference and the compositions of the instant claims are substantially the same. The reference anticipates the instant claims insofar as it discloses oral compositions, i.e., dentifrices and oral rinses that comprise polyphosphonates, anionic polymers, stannous ions and pyrophosphate salts to reduce staining due to stannous ions.

Obvious-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 5 of copending Application No. 10/975963. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both read on oral composition comprising a polymer, preferably a polyphosphate polymer, stannous ions and a fluoride source. The stannous ions in the instant claim are from stannous fluoride and/or other stannous salts, therefore fluoride ions exist in the compositions as in the claims of the copending application. The polymer comprised in the composition of the instant

claims are include at a range from 1% to 35% as recited in claim 3 of the copending application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2) Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of U.S. Patent No. 6,821,507. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both read on oral composition comprising a polymeric surface-active agent, stannous ions and a fluoride source. The stannous ions in the instant claims are from stannous fluoride and/or other stannous salts, therefore fluoride ions exist in the compositions as in the claims of the patent. The disclosure states the polymeric surface active agent of the compositions of the instant claims are include in a range from 1% to 35% as recited in claim 3 of the patent.

Claims 1-6 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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